

# Draft Guidance for Industry and FDA Staff

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## Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex

### *DRAFT GUIDANCE*

**This guidance document is being distributed for comment purposes only.  
Document issued on: November 14, 2005.**

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For questions regarding this document, contact John Farnham at 240-276-0115 or by email at [jjf@cdrh.fda.gov](mailto:jjf@cdrh.fda.gov).



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health

OB/GYN, Gastroenterology and Urology Devices Branch  
Division of Enforcement A, Office of Compliance

# Preface

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# **Draft Guidance for Industry and FDA Staff**

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## **Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex**

*This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.*

### **I. Introduction**

The Food and Drug Administration (FDA) has developed this draft guidance as a special controls guidance for male condoms made from natural rubber latex (latex condoms). This draft guidance will be issued in conjunction with a Federal Register notice announcing the proposal to amend the two existing classifications for condoms from class II (performance standards) to class II (special controls). The amended classifications would designate this labeling guidance document a special control for latex condoms, with or without spermicidal lubricant. This guidance is issued for comment purposes only. If a final rule to amend the classification for condoms is not issued, the final guidance document will not be issued.

This guidance document describes a means by which latex condoms may comply with the requirement of special controls for class II devices. FDA believes that adherence to the labeling recommendations described in this guidance document, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of latex condoms and, therefore, is proposing to designate this guidance as the special control for those devices. Following the implementation of a final rule amending the classification regulations for these devices, labeling on latex condoms

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with or without spermicidal lubricant will need to address the issues requiring special controls identified in this guidance document unless the device manufacturer in some other way provides equivalent assurances of safety and effectiveness.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

## **II. Background**

FDA believes that special controls, when combined with the general controls, will be sufficient to provide a reasonable assurance of the safety and effectiveness of latex condoms, with or without spermicidal lubricant. Thus, a manufacturer who intends to market a device of this type should (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the 510(k) requirements described in 21 CFR 807 Subpart E and the Quality Systems Regulation (21 CFR Part 820), and (2) address in user labeling the specific issues requiring special controls associated with these devices as identified in this draft guidance.

This draft special controls guidance document provides the classification and product codes for latex condoms (refer to Section IV). In addition, other sections of this draft guidance document list the issues requiring special controls identified by FDA and describe labeling measures that, if followed by manufacturers, will generally address the issues requiring special controls associated with these devices.

The labeling recommendations in this draft guidance document reflect an extensive review on the part of the Agency, in consultation with the National Institutes for Health (NIH) and the Centers for Disease Control and Prevention (CDC), of the available medical literature on the safety and effectiveness of condoms intended to prevent pregnancy and provide protection against sexually transmitted diseases (STDs). In addition, the Agency considered other relevant information related to the barrier properties of latex condoms and the various routes of transmission of STDs. A summary of FDA's review method and conclusions is described in the notice of proposed rulemaking for condoms and condoms with spermicidal lubricant that will publish in the same Federal Register that announces the availability of this draft guidance document. References are also provided in Section VIII of this guidance.

This draft guidance document also identifies issues requiring special controls related to nonoxynol-9 (N-9), used as a spermicide in the lubricant of some latex condoms, and provides labeling recommendations intended to help address these issues. These recommendations are based on the Agency's review of the literature related to N-9,

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including an extensive review by FDA's Center for Drug Evaluation and Research (CDER) of the possible health effects of N-9 on users of vaginal contraceptives. (Relevant references are provided in Section VIII of this guidance.)

### **III. Existing Labeling Requirements**

While this draft guidance document describes labeling *recommendations* regarding ways of meeting the proposed special control for latex condoms, there are also other specific labeling *requirements* for latex condoms contained in the following two regulations:

- User labeling for latex condoms (21 CFR 801.435)
- User labeling for devices that contain natural rubber (21 CFR 801.437)

Additionally, condom manufacturers must ensure that their devices meet the general labeling requirements for medical devices described in 21 CFR Part 801.

Existing labeling requirements for latex condoms include the following:

#### **A. Expiration date (21 CFR Section 801.435)**

The retail and primary condom package (individual foil) must include an expiration date that is no later than five years from the date of product packaging. This expiration date must be supported by shelf life data developed by the condom manufacturer. For details, please see 21 CFR 801.435, "*User labeling for latex condoms*," effective March 25, 1998. This regulation addresses the risk of condom deterioration due to product aging.

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**B. Caution regarding natural rubber latex and allergic reactions (21 CFR Section 801.437)**

Latex condoms, and all other devices composed of, or containing, natural rubber latex that contacts humans, are required to bear the following statement in bold print:

**Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.**

This statement must appear on all device labels, and other labeling, and must also appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper. For details, please see 21 CFR 801.437, “*User labeling for devices that contain natural rubber.*” This final rule became effective on September 30, 1998. This labeling requirement is necessary because devices composed of, or containing, natural rubber latex, pose a significant health risk to some individuals.

**C. General labeling requirements**

All devices, including condoms, are subject to the general labeling provisions described in 21 CFR part 801, Subpart A. Additionally, condoms are over-the-counter (OTC) devices, and are therefore subject to the requirements for OTC devices described in 21 CFR Part 801, Subpart C. You should familiarize yourself with these labeling requirements. This draft special controls guidance is consistent with these requirements and, in fact, some of the labeling terminology used in this draft guidance is described by these regulations.

Latex condoms must also include adequate directions for use to avoid being misbranded (section 502(f) of the Act, 21 U.S.C. 352(f); 21 CFR section 801.5). Adequate directions for use help ensure that the condom will be used correctly. The following set of statements is an example of acceptable directions for use for latex condoms:

- Put the condom on after the penis is fully erect and before intimate contact. Lesions, pre-ejaculate secretions, semen, vaginal secretions, saliva, urine, and feces can all transmit disease organisms.
- Place the condom on the head of the penis and unroll or pull it all the way to the base.
- If the condom doesn’t unroll, the wrong side was placed against the penis. Do not flip over. Throw it away and start over with a new condom.

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- Leave an empty space at the end of the condom to collect semen. Remove any air remaining in the tip of the condom by gently pressing the air out toward the base of the penis.
- After ejaculation and while the penis is still erect, hold onto the rim of the condom so that the condom does not slip off as the penis is carefully withdrawn.

For additional information on general labeling requirements, manufacturers are encouraged to consult with FDA's manual "Labeling: Regulatory Requirements for Medical Devices," (HHS Publication FDA 89-4203). This is available at the FDA website at <http://www.fda.gov/cdrh/dsma/470.pdf>. FDA has also included examples of labeling that incorporate the requirements of the Act and regulations and the recommendations made in this draft special controls guidance document in Section VII, below.

## **IV. Scope**

The scope of this special controls guidance document is limited to labeling for male condoms made from natural rubber latex. Such condoms are described in the two following classification regulations:

- Condom, 21 CFR 884.5300, Panel 85, product code HIS,
- Condom with Spermicidal Lubricant, 21 CFR 884.5310, Panel 85, product code LTZ.

This guidance is not intended to be a special control for male condoms made of natural membrane (skin) or synthetic materials. Because natural membrane and synthetic condoms differ in some respects from latex condoms, the present guidance document does not address all the labeling issues for these products. Until FDA provides further specific guidance for these products, manufacturers of synthetic condoms may consult Part C of FDA's guidance document, "Testing Guidance for Male Condoms made from New Material (June 29, 1995)," <http://www.fda.gov/cdrh/ode/oderp455.html>, and manufacturers of natural membrane condoms may consult the guidance document "Guidance for Industry -- Uniform Contraceptive Labeling (July 23, 1998)," <http://www.fda.gov/cdrh/ode/contrlab.html> <sup>1</sup>

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<sup>1</sup> These existing guidance documents for non-latex condoms do not currently address issues arising from the presence of nonoxynol-9 (N-9) in the spermicidal lubricant of some condoms made of these materials. FDA believes that the recommendations contained in this guidance regarding labeling to address N-9 in the spermicidal lubricant of latex condoms are also generally applicable to non-latex condoms containing N-9 in



## **V. Issues Requiring Special Controls**

FDA has identified the following issues requiring special controls associated with the use of latex condoms that can be mitigated by the labeling recommended in the draft special controls guidance. The recommended mitigation measures (labeling) are intended to provide information to users about the extent of protection provided by condoms to prevent pregnancy and prevent the spread of various types of STDs, as well as information about possible risks associated with certain uses of condoms with spermicidal lubricants containing nonoxynol-9 (N-9). The labeling provides important decision-making information for condom users to assist them in determining whether latex condoms are appropriate for their needs.

Table 1 includes risks associated with sexual intercourse, i.e., unintended pregnancy and STD transmission, that all latex condoms are intended to help prevent. This draft special controls guidance document addresses how manufacturers can label their condoms to help assure that they will be safe and effective for these intended uses, which are of significant personal and public health concern. Labeling for latex condoms with and without spermicidal lubricant should follow the mitigation measures suggested in Table 1. Table 2 identifies special issues associated with the spermicide, N-9. Labeling for latex condoms with N-9 in the lubricant should follow the recommended mitigation measures identified in Table 2, as well as Table 1. All the labeling recommendations are discussed in more detail in section VI.

### **A. Issues Requiring Special Controls and Recommended Mitigation Measures for Latex Condoms**

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the spermicidal lubricant, and encourages manufacturers of non-latex condoms containing N-9 to follow that aspect of this labeling guidance (see footnotes 2 and 3).

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**Table 1. Identified Issues and Recommended Mitigation Measures**

Identified issues <sup>A</sup>	Recommended mitigation measures
1. Risk of unintended pregnancy	<p>1. Labeling should indicate that condoms can reduce, but do not eliminate, the risk of pregnancy.</p> <p>Labeling should also include a table comparing pregnancy rates resulting from condom use to those resulting from other barrier contraceptive methods.</p>
<p>2. Risk of Transmission of Sexually Transmitted Diseases (STDs)</p> <p>2a. Human Immunodeficiency Virus (HIV/AIDS)</p> <p>2b. STDs can be transmitted in various ways, including transmission to or from the penis and transmission by other types of sexual contact.</p> <p>2c. STDs, such as chlamydia and gonorrhea, that are transmitted to or from the penis by contact with the vagina and genital fluids.</p> <p>2d. STDs, such as genital herpes and human papillomavirus (HPV) infection, that can be transmitted by contact with skin outside the area covered by a condom, as well as by contact with the penis.</p>	<p>2a. Labeling should indicate that latex condoms can greatly reduce, but do not eliminate, the risk of HIV transmission.</p> <p>2b. Labeling should indicate that latex condoms can help reduce the risk of STD transmission to or from the penis, but that some STDs can also be transmitted by other types of sexual contact.</p> <p>2c. Labeling should indicate that latex condoms can reduce the risk of STDs transmitted to or from the penis by contact with the vagina or genital fluids, such as chlamydia and gonorrhea.</p> <p>2d. Labeling should indicate that latex condoms provide less protection for those STDs that can also be transmitted by contact with skin outside the area covered by a condom, such as genital herpes and HPV. Labeling should clarify that consistent use of condoms may provide some benefit for these STDs, such as reduced risk of herpes infection or reduced risk of developing HPV-related diseases.</p>

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3. Incorrect or inconsistent use diminishing the effectiveness of condoms against the risks of unintended pregnancy and STD transmission.	3. Labeling should include adequate precautions.
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<sup>A</sup> Additional risks of (1) product deterioration due to aging and (2) allergic reactions to latex have been specifically addressed in labeling regulations that are discussed in Section III of this guidance.

**B. Issues Requiring Special Controls and Recommended Mitigation Measures Related to the Use of Nonoxynol-9 (N-9) in the Spermicidal Lubricant of Latex Condoms**

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**Table 2. Identified Issues and Recommended Mitigation Measures Related to N-9<sup>2</sup>**

Identified Issues	Recommended Mitigation Measures
<p>1. Actual benefits of N-9 may be less than the benefits perceived by some users.</p> <p>1a. Limited contraceptive benefits of N-9 contained in spermicidal lubricant.</p> <p>1b. N-9 in the lubricant of the condom does not protect against HIV/AIDS or other STDs.</p> <p>2. Risks associated with N-9 may outweigh benefits for some users.</p> <p>2a. N-9 can irritate the vagina. This may increase the risk of getting HIV/AIDS from an infected partner.</p> <p>2b. Latex condoms without N-9 should be used by those at risk of acquiring or transmitting (catching or spreading) HIV/AIDS.</p> <p>2c. N-9 can irritate the rectum. This may increase the risk of HIV transmission when used for anal sex.</p>	<p>1a. Labeling should include a statement that lubricant on the condom contains the spermicide nonoxonyl-9 (N-9), which kills sperm, but that the extent of pregnancy protection contributed by the N-9 has not been determined.</p> <p>1b. Labeling should include a statement that N-9 in the lubricant of the condom does not protect against HIV/AIDS or other STDs.</p> <p>2a. Labeling should inform users that use of N-9 can irritate the vagina and that this may increase the risk of getting HIV/AIDS from an infected partner.</p> <p>2b. Labeling should inform users that if they or their partner have HIV/AIDS, or if their infection status is unknown, they should choose a latex condom without N-9.</p> <p>2c. Labeling should inform users that condoms with N-9 should not be used for anal sex because N-9 can irritate the rectum and may increase the risk of getting HIV/AIDS from an infected partner.</p>

<sup>2</sup> FDA believes that the issues raised by the use of the spermicide N-9 in the lubricant of male condoms made of natural membrane or synthetic materials are very similar to the issues associated with N-9 used on latex condoms. Therefore, FDA recommends that manufacturers of synthetic condoms using N-9 implement all the identified mitigation measures related to N-9, and that manufacturers of natural membrane condoms with N-9 implement all the identified mitigation measures with the exception of item 2c of Table 2. Item 2c is not recommended for membrane condoms and could cause confusion because these condoms are only labeled for contraceptive use and include a specific statement that they do not provide protection against STDs (see "Guidance for Industry -- Uniform Contraceptive Labeling (July 23, 1998)," <http://www.fda.gov/cdrh/ode/contrlab.html>).

## VI. Labeling Recommendations

This section provides guidance on the labeling of latex condoms grouped according to the issues identified in Tables 1 and 2 of Section V of this document. Generally, there are three different levels of packaging for condoms:

- the retail package, including the principal display panel
- the primary condom package (individual foil)
- the package insert.

The recommendations in this section indicate the level(s) of packaging where the labeling should appear and provide examples of labeling statements that adequately address the issues identified in Tables 1 and 2.

### **A. Labeling Recommendations for Latex Condoms**

#### **1. Pregnancy**

Both the principal display panel of the retail package and the primary condom package (individual foil) should identify contraception as one of the principal intended actions of the latex condom. The following is an example of an acceptable statement:

*“When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy.”*

The package insert for latex condoms should include a similar statement under a heading identifying this as “Important information.”

The package insert should also contain a contraceptive effectiveness table comparing pregnancy rates associated with condom use with pregnancy rates for other barrier contraceptive methods. This information is intended to enable contraceptive users to compare alternatives and make appropriate choices. The following table [based on a table previously published in “Guidance for Industry -- Uniform Contraceptive Labeling (July 23, 1998),” <http://www.fda.gov/cdrh/ode/contrlab.html>] is recommended for the package insert of latex condoms:

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**Pregnancy Rates for Barrier Birth Control Methods**

***(For One Year of Use)***

*The following table provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies.*

***“Typical Use”*** rates mean that the method either was not always used correctly or was not used with every act of sexual intercourse or was used correctly but failed anyway.

<b><i>Method</i></b>	<b><i>Typical Use Rate of Pregnancy</i></b>
<b><i>No Method:</i></b>	85%
<b><i>Barrier Methods:</i></b>	
<i>Male Latex Condom Without Spermicide<sup>1</sup></i>	12%
<i>Diaphragm<sup>2</sup></i>	17%
<i>Cervical Cap (no previous births)<sup>2</sup></i>	17%
<i>Cervical Cap (previous births)<sup>2</sup></i>	30%
<i>Female Condom</i>	21%

<sup>1</sup> Typical pregnancy rates for a condom with spermicidal lubricant have not been determined.

<sup>2</sup> Used with spermicide.

## **2. Sexually Transmitted Diseases (STDs)**

### **2a. Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS)**

The principal display panel, the package insert, and the primary condom package (individual foil) should identify protection from HIV/AIDS as one of the principal intended actions of the latex condom. The following is an example of an acceptable statement:

*“When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of catching or spreading HIV, the virus that causes AIDS.”*

Since the available evidence indicates that latex condoms can effectively reduce

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transmission of HIV/AIDS as well as prevent pregnancy, these two principal intended uses may be combined into one statement such as:

*“When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy and the risk of catching or spreading HIV, the virus that causes AIDS.”*

If a combined statement is used, this statement should appear on the principal display panel, on the primary condom package (individual foil), and in the package insert under a heading identifying this as “Important information.”

#### 2b. STDs can be transmitted in various ways, including transmission to or from the penis and transmission by other types of sexual contact

The retail package of condoms should indicate that there are many types of STDs and that latex condoms can help prevent the transmission of STDs that are spread to or from the penis. The labeling should also explain that some STDs may also be spread by other types of sexual contact. The following is an example of an acceptable statement:

*“Important information: There are many types of sexually transmitted diseases (STDs) and different ways of catching or spreading infection. A latex condom can reduce the risk of STD transmission to or from the penis. However, some STDs can also be spread by other types of sexual contact. For additional information on STD protection, please read the enclosed insert.”*

This statement should be prominently displayed on the retail package, but may appear on a panel other than the principal display panel.

#### 2c. STDs transmitted to or from the penis by contact with the vagina and genital fluids

The package insert should include a statement explaining that latex condoms can help prevent the transmission of STDs that are spread to or from the penis by contact with the vagina and genital fluids. This statement should include specific examples of diseases that are spread in this manner, such as chlamydia and gonorrhea. The statement should appear in the package insert under a heading identifying this as “Important information.” This statement should also refer the user to additional sources of information on STDs such as a health care provider or other information provided by government public health agencies. The following is an example of an acceptable statement:

*“Important information: Latex condoms can reduce the risk of sexually transmitted diseases (STDs), such as chlamydia and gonorrhea, that are spread to*

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*or from the penis by direct contact with the vagina and genital fluids. For more information on STDs, consult your health care provider or information provided by government public health agencies."*

2d. STDs transmissible by contact outside the area covered by a condom

The package insert should indicate that condoms provide less protection for certain STDs, including genital herpes and human papillomavirus (HPV) infection, that can also be spread by contact with infected skin outside the area covered by the condom. Condoms cannot protect against these STDs when they are spread in this way. Using latex condoms every time you have sex may still give some benefits against these STDs. For example, using a condom may lower the risk of catching or spreading genital herpes. Using a condom also may lower the risk of developing HPV-related diseases, such as genital warts and cervical cancer. The statement should appear in the package insert under a heading identifying this as "Important information." The statement should also refer the user to additional sources of information on STDs such as a health care provider and/or other information provided by government public health agencies.

The following is an example of an acceptable statement:

*"Important information: Condoms provide less protection for certain STDs, including genital herpes and human papillomavirus (HPV) infection, that can also be spread by contact with infected skin outside the area covered by the condom. Condoms cannot protect against these STDs when they are spread in this way. Using latex condoms every time you have sex may still give you some benefits against these STDs. For example, using a condom may lower your risk of catching or spreading genital herpes. Using a condom also may lower your risk of developing HPV-related diseases, such as genital warts and cervical cancer. For more information, consult your health care provider or information provided by government public health agencies."*

The statements recommended for the package insert in 2a, 2c, and 2d above could be combined into one package insert statement that would address all the applicable identified risks of pregnancy and STDs, such as:

*"Important information:*

*When used correctly every time you have sex, latex condoms greatly reduce,*



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*but do not eliminate, the risk of pregnancy and the risk of catching or spreading HIV, the virus that causes AIDS. Latex condoms can also reduce the risk of other sexually transmitted diseases (STDs), such as chlamydia and gonorrhea, that are spread to or from the penis by direct contact with the vagina and genital fluids.*

*Condoms provide less protection for certain STDs, including genital herpes and human papillomavirus (HPV) infection, that can also be spread by contact with infected skin outside the area covered by the condom. Condoms cannot protect against these STDs when they are spread in this way. Using latex condoms every time you have sex may still give you some benefits against these STDs. For example, using a condom may lower your risk of catching or spreading genital herpes. Using a condom also may lower your risk of developing HPV-related diseases, such as genital warts and cervical cancer.*

*For more information on STDs, consult your health care provider or information provided by government public health agencies.”*

### **3. Incorrect or Inconsistent Use**

The package insert should include appropriate precautions. The following set of statements is an example of acceptable precautions regarding condom use:

- *Use a new condom every time you have sexual intercourse or other acts between partners that involve contact with the penis.*
- *Do not reuse condoms.*
- *Store condoms in a cool, dry place.*
- *If the rubber material is sticky or brittle or obviously damaged, do not use the condom.*
- *If a lubricant is wanted, use water-based lubricants such as [name of product]. DO NOT USE OIL-BASED LUBRICANTS, such as those made with petroleum jelly (e.g., Vaseline®), mineral oil, vegetable oil, or cold cream, as these may damage the condom.*

Manufacturers may have additional precautions or other information that they believe is necessary for proper use of their products. Such additional information is acceptable as long as it does not conflict with or detract from the statements recommended in this guidance (or equivalent statements) or any other applicable requirements (see Section III).

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**B. Labeling Recommendations Related to the Use of N-9 in Condoms with Spermicidal Lubricant**

As already noted, latex condoms are classified under one of two classification regulations, depending upon whether or not they contain a spermicidal lubricant. The following discussion and special control labeling recommendations apply only to latex condoms classified under 21 CFR 884.5310 and containing a lubricant with N-9.<sup>3</sup>

Since 1982, condoms with N-9 have been required to bear a contraceptive effectiveness statement to be classified under 21 CFR 884.5310. This contraceptive effectiveness statement was part of the reclassification order for a condom with spermicidal lubricant (see 47 FR 49201, Oct. 29, 1982). Subsequently, new information has been developed regarding the potential for N-9 to contribute to adverse health consequences in some circumstances (see References in Section VIII, below). This new information demonstrates that there are risks associated with N-9 that may outweigh its benefit as a spermicide for some users.

Through this special control, FDA is providing important decision-making information and cautions, based upon this new information, that will permit users to determine whether a latex condom containing N-9 is appropriate for their needs. This special control, which addresses the new information developed since the 1982 reclassification of condoms with spermicidal lubricant into class II, together with the general controls, should reasonably assure the safety and effectiveness of such condoms. FDA's current thinking on appropriate cautionary statements for latex condoms containing N-9 follows. When this guidance becomes final and effective as a special control, it will supersede the contraceptive effectiveness statement described in the reclassification order and in the October 29, 1982, Federal Register notice.<sup>4</sup>

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<sup>3</sup> Although this guidance document is not designated as a special control for condoms made of materials other than latex, FDA recommends (for the reasons described above in footnote 2) that manufacturers of synthetic condoms using N-9 follow all the labeling suggestions related to N-9, and that manufacturers of natural membrane condoms with N-9 follow all the N-9 labeling suggestions with the exception of the recommended anal use warning. The anal use warning is not recommended for membrane condoms and could be confusing because these condoms are labeled only for contraceptive use and include a specific statement that they do not provide protection against STDs (see "Guidance for Industry -- Uniform Contraceptive Labeling (July 23, 1998),"

<http://www.fda.gov/cdrh/ode/contrlab.html>).

<sup>4</sup> When final, this draft special controls guidance document will also supersede FDA recommendations in the FDA letter to "All U.S. Condom Manufacturers, Importers, and Repackagers" (April 7, 1987) and the FDA letter to "Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention" (February 13, 1989).

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#### 1a. Limited benefits of N-9

The retail package of latex condoms with N-9 should include a statement indicating that the lubricant on the condom contains N-9, which kills sperm, but that the extent of pregnancy protection contributed by the N-9 has not been measured. This statement should be prominently displayed on the retail package, but may appear on a panel other than the principal display panel. The following is an example of an acceptable statement:

*“The lubricant on this condom contains the spermicide nonoxynol-9 (N-9), which kills sperm; however, the amount of additional pregnancy protection provided by the N-9 has not been measured.”*

Note: The abbreviation “N-9” may be used to save space on labeling but the first reference to “nonoxynol-9” on each package panel should be spelled out.

A similar statement should also appear on the primary condom package (individual foil) as well as in the package insert.

#### 1b. N-9 does not protect against HIV/AIDS or other Sexually Transmitted Diseases

The retail package of latex condoms with N-9 should include a statement that the N-9 in the product does not provide protection from HIV/AIDS or other sexually transmitted diseases. This statement should be prominently displayed on the retail package, but may appear on a panel other than the principal display panel. The following is an example of an acceptable statement:

*“The nonoxynol-9 (N-9) lubricant on this condom does not protect against HIV/AIDS or other sexually transmitted diseases.”*

A similar statement should also appear on the primary condom package (individual foil) as well as in the package insert.

#### 2a. Risks of N-9 irritation and transmission of HIV/AIDS

A risk statement addressing vaginal irritation and HIV/AIDS transmission should appear on the retail package. This risk statement should be prefaced by the words “Nonoxynol-9 Warning” and should inform users of the risk of vaginal irritation and possible increased risk of transmission of HIV/AIDS from an infected partner. The following is an example of an acceptable statement:

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***“Nonoxynol-9 Warning:*** *The spermicide nonoxynol-9 (N-9) can irritate the vagina. This may increase the risk of getting HIV/AIDS from an infected partner.*

A similar statement should appear in the package insert.

**2b. Users at risk of catching or spreading HIV/AIDS should choose latex condoms without N-9**

The retail package of latex condoms containing N-9 should include a statement informing users that if they or their partner have HIV/AIDS, or if their infection status is unknown, they should choose a latex condom without N-9. This statement should be prefaced by the words “Nonoxynol-9 Warning.” The following is an example of an acceptable statement:

***Nonoxynol-9 Warning:*** *If you or your partner has HIV/AIDS, or if you do not know if you or your partner is infected, you should choose a latex condom without nonoxynol-9 (N-9).*

A similar statement should appear in the package insert.

**2c. Risks of anal use of condoms with N-9**

The retail package of latex condoms containing N-9 should include a statement informing users that N-9 can irritate the rectum and they should not use condoms with N-9 for anal sex. This statement should be prefaced by the words “Nonoxynol-9 Warning,” and should be prominently displayed on the retail package, but may appear on a panel other than the principal display panel. The following is an example of an acceptable statement:

***“Nonoxynol-9 Warning:*** *You should not use condoms with nonoxynol-9 (N-9) for anal sex. N-9 can irritate the rectum and may increase the risk of getting HIV/AIDS from an infected partner.*

A similar statement should appear in the package insert.

Where package space permits, the agency encourages a combined N-9 statement such as:

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*“The lubricant on this condom contains the spermicide nonoxynol-9 (N-9), which kills sperm; however, the amount of additional pregnancy protection provided by the N-9 has not been measured.*

*The N-9 lubricant on this condom does not protect against HIV/AIDS or other sexually transmitted diseases.*

***N-9 Warning:***

- *N-9 can irritate the vagina. This may increase the risk of getting HIV/AIDS from an infected partner.*
- *If you or your partner has HIV/AIDS, or if you do not know if you or your partner is infected, you should choose a latex condom without N-9.*
- *You should not use condoms with N-9 for anal sex. N-9 can irritate the rectum and may increase the risk of getting HIV/AIDS from an infected partner.*

The agency recognizes that there may not be sufficient space on the primary condom package (individual foil) to include the recommended warning statements for N-9 outlined in 2a, 2b, and 2c and therefore recommends that the primary condom package include a statement referring the user to the package or package insert for more information on N-9 such as:

*“For more important information on N-9, please read the box or package insert.”*

Where possible, this statement should appear directly after the labeling on the individual condom package that addresses the 1a and 1b issues.

## **VII. Examples of Condom Labeling that Follow the Recommendations in the Draft Guidance**

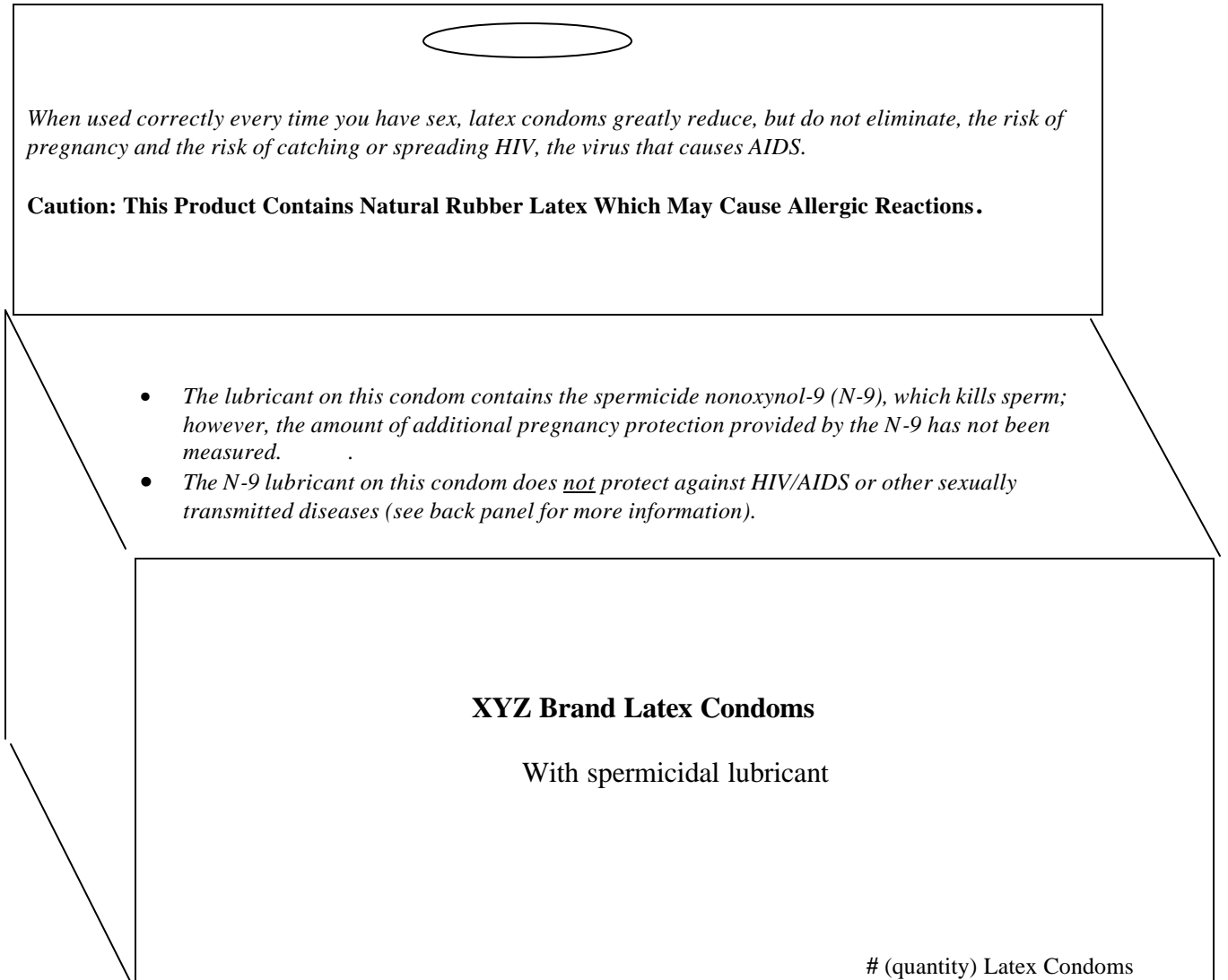
The examples in this section are for a condom with nonoxynol-9 in order to show all of the labeling potentially applicable to a latex condom.

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Label statements appearing in *italics* are those recommended in Section VI of the current guidance. Other label statements, discussed in Section III of this guidance, appear in regular font. This difference in font styles is used only to identify the labeling recommended by this guidance as a special control. FDA is not recommending italic font for the actual label statements provided by manufacturers.

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**Front panels of condom retail package:**



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**Rear panel of condom retail package**

*Important information: There are many types of sexually transmitted diseases (STDs) and different ways of catching or spreading infection. A latex condom can reduce the risk of STD transmission to or from the penis. However, some STDs can also be spread by other types of sexual contact. For additional information on STD protection, please read the enclosed insert.*

***Nonoxynol-9 Warning:***

- The spermicide nonoxynol-9 (N-9) can irritate the vagina. This may increase the risk of getting HIV/AIDS from an infected partner.*
- If you or your partner has HIV/AIDS, or if you do not know if you or your partner is infected, you should choose a latex condom without N-9.*
- You should not use condoms with N-9 for anal sex. N-9 can irritate the rectum and may increase the risk of getting HIV/AIDS from an infected partner.*

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Rockville, Maryland*

*EXP. Date: Jan 20XX*



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**Primary condom package (individual foil):**

**Front of packet**

**One XYZ Brand  
Latex Condom with spermicidal  
lubricant**

*When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy and the risk of catching or spreading HIV, the virus that causes AIDS.*

**Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.**

**Back of packet**

*The lubricant on this condom contains the spermicide nonoxynol-9 (N-9), which kills sperm; however, the amount of additional pregnancy protection provided by the N-9 has not been measured. The N-9 lubricant on this condom does not protect against HIV/AIDS or other sexually transmitted diseases.*

*For more important information on N-9, please read the box or package insert.*

Distributed by ABC Corporation  
Rockville, Maryland

EXP Date: Jan 20XX

**Package Insert:**

*Directions for use:*

- *Put the condom on after the penis is fully erect and before intimate contact. Lesions, pre-ejaculate secretions, semen, vaginal secretions, saliva, urine, and feces can all transmit disease organisms.*
- *Place the condom on the head of the penis and unroll or pull it all the way to the base.*
- *If the condom doesn't unroll, the wrong side was placed against the penis. Do not flip the condom over. Throw it away and start over with a new condom.*
- *Leave an empty space at the end of the condom to collect semen. Remove any air remaining in the tip of the condom by gently pressing the air out toward the base of the penis.*
- *After ejaculation and while the penis is still erect, hold onto the rim of the condom so that the condom does not slip off as the penis is carefully withdrawn.*

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### **Package insert (cont.)**

#### *Precautions:*

- *Use a new condom every time you have sexual intercourse or other acts between partners that involve contact with the penis.*
- *Do not reuse condoms.*
- *Store condoms in a cool, dry place.*
- *If the rubber material is sticky or brittle or obviously damaged, do not use the condom.*
- *If a lubricant is wanted, use water-based lubricants such as [name of product]. DO NOT USE OIL-BASED LUBRICANTS, such as those made with petroleum jelly (e.g., Vaseline®), mineral oil, vegetable oil, or cold cream, as these may damage the condom.*

#### *Important information:*

*When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy and the risk of catching or spreading HIV, the virus that causes AIDS. Latex condoms can also reduce the risk of other sexually transmitted diseases (STDs), such as chlamydia and gonorrhea, that are spread to or from the penis by direct contact with the vagina and genital fluids.*

*Condoms provide less protection for certain STDs, including genital herpes and human papillomavirus (HPV) infection, that can also be spread by contact with infected skin outside the area covered by the condom. Condoms cannot protect against these STDs when they are spread in this way. Using latex condoms every time you have sex may still give you some benefits against these STDs. For example, using a condom may lower your risk of catching or spreading genital herpes. Using a condom also may lower your risk of developing HPV-related diseases, such as genital warts and cervical cancer.*

*For more information on STDs, consult your health care provider or information provided by government public health agencies.*

#### *Nonoxynol-9*

*The lubricant on this condom contains the spermicide nonoxynol-9 (N-9), which kills sperm; however, the amount of additional pregnancy protection provided by the N-9 has not been measured.*

*The N-9 lubricant on this condom does not protect against HIV/AIDS or other sexually transmitted diseases.*

#### *N-9 Warning:*

- *N-9 can irritate the vagina. This may increase the risk of getting HIV/AIDS from an infected partner.*
- *If you or your partner has HIV/AIDS, or if you do not know if you or your partner is infected, you should choose a latex condom without N-9.*
- *You should not use condoms with N-9 for anal sex. N-9 can irritate the rectum and may increase the risk of getting HIV/AIDS from an infected partner.*

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**Package insert (cont)**

**Pregnancy Rates for Barrier Birth Control Methods**

***(For One Year of Use)***

*The following table provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies.*

***“Typical Use”*** rates mean that the method either was not always used correctly or was not used with every act of sexual intercourse or was used correctly but failed anyway.

<b><i>Method</i></b>	<b><i>Typical Use Rate of Pregnancy</i></b>
<b><i>No Method:</i></b>	85%
<b><i>Barrier Methods:</i></b>	
<i>Male Latex Condom Without Spermicide<sup>1</sup></i>	12%
<i>Diaphragm<sup>2</sup></i>	17%
<i>Cervical Cap (no previous births)<sup>2</sup></i>	17%
<i>Cervical Cap (previous births)<sup>2</sup></i>	30%
<i>Female Condom</i>	21%

<sup>1</sup> Typical pregnancy rates for a condom with spermicidal lubricant have not been determined.

<sup>2</sup> Used with spermicide.

## **VIII. References**

### **Condom protection against STDs**

1. NIH/CDC/FDA workshop on condom effectiveness (held June 2000, summary available June 2001) <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>

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2. CDC STD Treatment Guidelines 2002,  
<http://www.cdc.gov/std/treatment/default.htm>
3. FDA review of currently available literature related to condom effectiveness. A bibliography is provided in the notice of proposed rulemaking for condoms and condoms with spermicidal lubricant that will publish in the same Federal Register that announces the availability of this draft guidance document.

Nonoxynol-9

4. FDA monograph on nonoxynol-9
5. WHO/CONRAD Technical Consultation on Nonoxynol-9 (June 25, 2002)  
[http://www.who.int/reproductive-health/publications/rhr\\_03\\_8/Nonoxynol\\_9.pdf](http://www.who.int/reproductive-health/publications/rhr_03_8/Nonoxynol_9.pdf)
6. OTC Vaginal Contraceptive Drug Products containing Nonoxynol-9; Required Labeling, Proposed Rule. Federal Register, Vol 68, No. 11, January 16, 2003, pp 2254-2262.  
[http://www.fda.gov/cder/otcmonographs/Vaginal\\_Contraceptive/vaginal\\_contraceptive\\_N9\\_PR\\_20030116.htm](http://www.fda.gov/cder/otcmonographs/Vaginal_Contraceptive/vaginal_contraceptive_N9_PR_20030116.htm)
7. Phillips D. Nonoxynol-9 enhances rectal infection by herpes simplex virus in mice. Contraception 1998; 57: 341-348.
8. Tabet SR, Surawicz C, Horton S et al. Safety and toxicity of Nonoxynol-9 gel as a rectal microbicide. Sexually Transmitted Diseases 1999; 26: 10: 564-571.
9. Phillips D. Nonoxynol-9 causes rapid exfoliation of sheets of rectal epithelium. Contraception 2000; 62: 3: 149-154.